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EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/30/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

89/030510

Applicant(s)

Herrmann

Examiner

J.M. Ford

Group Art Unit

1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on April 18, 2003
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-6 is/are pending in the application.
- Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- ☒ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 5 and 6 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☒ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).
- *Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1624

Applicant's response and election of claims 1, 2, 5 and 6 is noted in a letter of April 18, 2003.

Claims 3 and 4 stand withdrawn, as being directed to multiple methods of preparing the compounds of claim 1. MPEP 806.05(f) provide for restriction under such circumstances.

The restriction requirement is considered sound and proper, and will be maintained.

Claims 5 and 6 are rejected under 35 U.S.C. 112, 2nd paragraph, as they are not written in proper U.S. claim form.

Claim 5 should read: 5. A pharmaceutical composition comprising one or more compounds of claim 1 and an inert carrier.

The utility statement in claim 6 is not acceptable. Collogenase/MMP-inhibiting activities is not a real world activity.

This utility statement is not acceptable, as it does not relate to the real ~~World~~ of commerce.

The recent utility guidelines set by ^{the US}PTO require applicants to meet the requirements as stated in Brenner v. Manson in, 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be

Art Unit: 1624

capable of practical employment". This language is echoed in *Bindra vs. Kelly*, 206 USPQ 570.

A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

The PTO has amended the guidelines to clarify "specific utility". The court focused on the fact that the applicant failed to identify a "specific utility" in *Brenner v. Manson*.

This requirement of one specific utility is consistent with Unity of Invention Practice in ~~International~~ Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Examples of utility expressions that have been held to be insufficient are: A disclosure that the claimed compounds can be used for "technical and pharmaceutical purpose" does not meet the requirements of 35 U.S.C. 112. *In re Dietrich* (CCPA 1963) 318 F2d 946, 138 USPQ 128.

The expressions "biological activity" and "biological properties" are too nebulous to meet the requirements of 35 U.S.C. 112. *In re Kirk et al.* (CCPA 1967) 376 F2d 936, 153 USPQ 48. Same, <<good effects against a very wide range of insects>>. *In re Lorenz et al.* (CCPA 1962) 305 F2d 875, 134 USPQ 312.

The <<how to use>>requirements of 35 U.S.C. 112 are not met by disclosing only a pharmacological activity of the claimed compounds, if one skilled in the art would not be able to use the compounds effectively without undue experimentation. *In re Dietrich* (CCPA 1963) 318 F2d 946, 138 USPQ 128, *In re Gardner et al.* (CCPA 1970)

Art Unit: 1624

427 F2d 786, 166 USPQ 138. Thus, where the claimed compounds are not structurally similar to known compounds having the same activity and their pharmaceutical properties could not be predicted from their chemical structure, a disclosure that they possess a particular activity may not suffice as a description of how to use as required by 35 U.S.C. 112. In re Moureu et al. (CCPA 1965) 345 F2d 595, 145 USPQ 452.

Statements of Utility which relate to or imply the treatment of a disease are subject to closer scrutiny; Ex parte Moore et al. (POBA 1960) 128 USPQ 8. Thus, when the disclosed utility is the production of a physiological response, e.g., antidepressant effect, the dosage effective to achieve this response in a host, whether human or animal, must be disclosed. In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 U.S.P.Q. 138.

This requirement of one specific utility is consistent with the Unity of Invention practice in International Applications and National Phase Applications under 35 U.S.C. 371.

Examples of terms and expressions that do not satisfy 35 U.S.C. 112, 1st paragraph, are statement that a product is a "pharmaceutical", "therapeutic agent", In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128; In re Lorenz et al. (CCPA 1962) 305 F2d 875, 135 F2d 875, 135 USPQ 312 and Ex parte Brokmann et al. (POBA 1959) 127 USPQ 57 ; In re Kirk et al. (CCPA 1967) 153 USPQ 48; and In re Joly et al. (CCPA 1967) 376 F2d 906, 153 USPQ 45.

Art Unit: 1624

A specification, which discloses only one mode of administration of a medical for the purpose of effecting a modification in a body function, does not provide for a claim not direction to that specific mode. Ex parte Proctor (POPA 1996 158 USPQ 677).

A claim, which designates the amount of an ingredient of a claimed composition as "an effective amount", is too broad and indefinite if it does not designate of intended effect. Ex parte Dobson et al. (POBA 1969) 165 USPQ 29. In re Fredriksen, 102 USPA 35, (CCPA 1954).

Issenstead v. Watson, (DCDC 1957) 269 F. Supp 630, 155 USPQ 630. 155 USPQ 838. Noted where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev v. Brenner Ferguson, (POBA 1957), 177 USPQ 229. Where utility is based on the alleged enhancement of activity of known medicines, the CCPA upheld the Examiner's requirement that the applicant submit evidence, which substantiated the allegation, unless one skilled in the art would accept them as obviously valid and correct. In re Novak et al., (CCPA 1962), 306 F2d 924, 134 USPQ 335.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use ^{and} require proof thereof, when such use is a medical nature for the treatment of a serious disease. Ex parte Moore et al.,

Art Unit: 1624

(POBA 1960) 128 USPQ 8 ; In re Citron. (CCPA et al.) 325 F2d 248, 139 USPQ 516 ;
In parte Hartop et al., (CCPA 1962) 311 F2D 249, 135 USPQ 419.

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals.

Brenner, Comr., Pats. Vs. Manson, (USSC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility consists of its potential role as an object of use-testing, reasoning the patent system is related to the World of Commerce, rather than the realm of philosophy ibid, 148 USPQ at 696.

Assay tests or laboratory screen test are not acceptable.

A Broad statement of utility, as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

The U.S. PTO, has amended the guidelines to clarify "specific utility". The focus was on Brenner v. Manson. The utility need be one in the real World Commerce.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug by the Food and Drug Administration and by the American Medical Association Council on Pharmacy, were alleged in the specification; Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven types of cancer with a member of a class of several compounds; In re Buting, (CCPA 1969) 418 F2d 540, 163 USPQ 689.

Art Unit: 1624

Claims 1 and 2 are rejected under 35 U.S.C. 103 as being unpatentable over the art cited on the 1449 form. The instances where R3 and X are -SH are shown by the disclosures of the patents cited.

Removal of alk being 3 - methyl propylene does not remove the analogous alkylene radicals from being obvious variations.

The next adjacent compound would be structurally obvious. See, In re Dillon, 919 F.2d at 696, 16 U.S.P.Q. 29 at 1904. See also Deuel, 51 F.3d at 1558, 34 U.S.P.Q. at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compounds. For example, one compound may suggest its homologs, because homologs often have similar properties, and, therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

Other structural similarities have been found to support a prima facie case of obviousness. E.g., In re May, 574 F.2d 1082, 1093-95, 197 U.S.P.Q. 601, 610-11 (CCPA 1978) (stereo isomers); In re Wilder, 563 F.2d 457, 460, 195 U.S.P.Q. 601, 610-11 (CCPA 1977) (adjacent homologs and structural isomers); In re Hoch, 428 F.2d 1341, 1344, 166 U.S.P.Q. 406, 409 (CCPA 1970) (acid and ethyl ester); In re Druey, 319 F.2d 237, 240, 138 U.S.P.Q. 38, 41 (CCPA 1963) (omission of methyl group from pyrazole ring).

A compound need not be a homolog or isomer of a prior art compound in order to be susceptible to a rejection based on structural obviousness.

Art Unit: 1624

A method of reducing sunburn by means of applying an effective amount of a compound of claim 1 to skin in need of such protection. —is suggested in lieu of claim 6. This is taken ~~from~~ page 4, last paragraph of the specification.

Applicants may not petition the restriction requirement until the requirement is made Final. See 37 CFR 1.499 and 1.144. This is the first action on the merits, nothing has been made Final.

If claims 3 and 4 are cancelled and replaced with one process of preparing the compounds of claim 1, consistent with 37 CFR 1.475, it will be examined with the compounds of claim 1. It may become necessary to limit claim 1 to one A variable, because it is so large an area, being benzene and thiophene. It appears *also that the* claim is not clear, ~~that~~ certain cyclo alkyl rings may also be (A).

John M. Ford: jmr

July 28, 2003



JOHN M. FORD
PRIMARY EXAMINER

Group Art Unit 1624